K043096
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SECTION 5. SUMMARY AND CERTIFICATION

A. DEVICE SUMMARY

Summary of Safety and Effectiveness

The following information constitutes the summary for the Commander II.

SUBMITTERS NAME:	Cardiocom, LLC.
ADDRESS:	1260 Park Road, Chanhassen, Minnesota 55317
CONTACT PERSON:	Constance G. Bundy
TELEPHONE NUMBER:	(763) 574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION	Prepared October 15th, 2004

1. **Identification of device**
   Proprietary Name: Commander II
   Common Name: Noninvasive blood pressure measurement system
   Classification Status: Class II per regulations 870.1130
   Product Code: DXN

2. **Description of the Device**
   The Commander II is an automated device that connects to the user's telephone system at home. It has a display that asks the user health related questions and has inputs for devices such as weight scales, blood pressure meters, and other vital sign measurement devices.

3. **Intended use**
   The Commander II device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.

4. **Technological characteristics, comparison to predicate device.**
   The Commander II is substantially equivalent to: Home Care Monitoring System, AvidCare Corp., K010029. The Commander II device and its predicate system have the same general use to provide the capability for health care professionals to monitor the vitals signs of their patients from remote locations.

5. Discussion of functional and safety testing.

The device has been tested according to the following standards:

• EN60601-1-2, 2001	EMC Emissions EMC Immunity
• EN61000-3-2	Limits for Harmonic Current Emissions
• FCC Part 68	Connection of Terminal Equipment to the Telephone Network
• UL and C-UL Listing Mark	UL Safety Standards

Verification and validation testing was conducted to establish performance and reliability characteristics of the device.

6. Conclusion

Based on the low risk device type, internal and external performance testing, it is Cardiocom's conclusion that Commander II presents no significant concerns about safety and effectiveness.

B. TRUTH AND ACCURACY CERTIFICATION

I certify that, in my capacity as President, I believe, to the best of my knowledge, that all data and information maintained on file are truthful and accurate, and that no material fact has been omitted.

10/15/04

Daniel L. Cosentino, MBA
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Cardiocom
c/o Mr. Pedro E. Gonzales
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K043096
Trade Name: Commander II
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: November 03, 2004
Received: November 09, 2004

Dear Mr. Gonzales:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043096

B. INDICATIONS FOR USE

510(k) Number K043096

Device Name: Commander II

Indications for Use:
The Commander II device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.

Contraindications, Precautions and Warnings:
The Commander II device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted. The Commander II is not intended as a substitute for medical care.

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043096